Tentative approval of nevirapine oral suspension (pediatric)

The Food and Drug Administration (FDA), on December 27, 2005, granted tentative approval, through an expedited procedure, to generic Nevirapine Oral Suspension, 50 mg/5 mL, manufactured by Aurobindo Pharma LTD., of Hyderabad, India. This product is a generic version of the approved product, Viramune Oral Suspension, 50 mg/5 mL, manufactured by Boehringer Ingelheim Pharmaceuticals. It is indicated for use in pediatric patients with HIV.

Nevirapine is active against the human immunodeficiency virus (HIV) that causes AIDS. It is in the class of drugs called nonnucleoside reverse transcriptase inhibitors (NNRTIs), which helps keep the AIDS virus from reproducing. It is used in combination with other antiretroviral agents for the treatment of HIV-1 infection.

FDA tentative approval means that although existing patents and/or exclusivity prevent marketing of this product in the U.S., it meets all of FDA's manufacturing quality and clinical safety and efficacy standards required for marketing in the U.S. As with all generic application assessments, FDA conducts an on-site inspection of each manufacturing facility and of the facilities performing the bioequivalence studies prior to granting approval or tentative approval to these applications to assess the ability of the manufacturer to produce a quality product and to assess the quality of the bioequivalence data supporting the application.

Tentative approval by FDA means that this product will now be available for consideration for purchase under the President's Emergency Plan for AIDS Relief (PEPFAR).

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